NDA 8-085/S-051
NDA 11-719/S-100

Lederle Parenterals, Inc.
Attention: Nanette E. Holston
P.O. Box 8299
Philadelphia, Pennsylvania 19101

Dear Ms. Holston:

Please refer to your supplemental new drug applications dated February 10, 2000, received February 15, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for for Methotrexate Sodium Tablets, Methotrexate Sodium for Injection and Methotrexate Sodium Injection.

These supplemental new drug applications provide for revisions concerning Mycosis Fungoides.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must include the agreed upon labeling text provided in our February 20, 2001 communication.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplements NDA 8085/S-051 and NDA 11-719/S-100." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Paul Zimmerman, Project Manager, at (301) 594-5775.

Sincerely,

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research